Current Status of Useful Written Prescription Drug Information for Patients

Summary of Public Workshop

February 29-March 1, 2000

Participants in a public workshop concluded FDA should find a way to include consumer input in its upcoming evaluation of the usefulness of written information dispensed with prescription drugs. About 150 representatives from consumer groups, professional societies, trade associations and the industry gathered Feb. 29 and March 1 to provide FDA officials with feedback on a preliminary study conducted last year that may serve as a model for this year's assessment. The docket for accepting feedback from the public (00N-0352) will be open until April 28, 2000.

The study found that nearly 87 percent of new prescriptions were dispensed with some written information in addition to the label and stickers on the medication container. However, the study concluded that the quality of the information was variable with many areas for improvement.

Participants made a number of wide-ranging recommendations. "A lot of what we are hearing would constitute an expensive undertaking," said Nancy Ostrove, Ph.D., moderator of the workshop. Ostrove, from the Division of Drug Marketing, Advertising and Communications in FDA's Center for Drug Evaluation and Research, will spearhead the Agency's efforts on this year's study.

FDA will sort through the recommendations and "clearly go in the direction of consensus," she said. The Agency will do what is in the public health interest in areas lacking consensus and conduct the best study it can within the constraints of resources.

Before any other initiatives can be proposed by FDA, it must first evaluate the success of a public-private action plan that is designed to provide patients with better and easy-to-read written information about their prescription drugs. The plan's goal is for "useful" written information to be given to 75 percent of persons receiving new prescriptions by the year 2000. The goal rises to 95 percent by 2006.

A copy of the study report, a transcript of the meeting and other background information is available on FDA's Web site at

http://www.fda.gov/cder/calendar/meeting/rx2000

The workshop included presentations on the background leading up to the study, the study itself, public questions and comments about the study and breakout sessions to solicit suggestions and recommendations for the large-scale study.

Background

Thomas J. McGinnis, R.Ph., from FDA's Office of Policy, provided historical background leading to a 1995 proposed rule that would have required the pharmaceutical industry to develop consumer-oriented leaflets, known as "medication guides." The concept of dispensing patient information sheets along with prescription drugs was born in the late 1960s, and it gained support from consumer groups and public health officials through the 1970s. Industry and pharmacists, however, balked at the notion of maintaining an inventory of thousands of consumer leaflets in each corner drugstore across the country.

By the mid-1990s, information technology available in nearly all drugstores precluded the need to store preprinted sheets, and the FDA issued a proposal that set specific goals and time frames for the distribution of patient medication information for private-sector initiatives to meet. A 1996 law (P.L. 104-180) preempted a final regulation and, instead, called for voluntary distribution of leaflets through private-sector efforts. Only if the voluntary effort failed could FDA take further action.

The law allowed six months for a private-public collaboration to develop an action plan to achieve goals consistent with those of the proposed rule. It said that useful information must be easily understood, scientifically accurate and nonpromotional in tone and content.

HHS called on the Keystone Center, a public policy and educational organization, to facilitate consensus on the action plan. The center's Judith O'Brien summarized the consensus building work that involved public meetings and a 34-member steering committee. Committee members represented the pharmaceutical industry, pharmacists, physicians, database companies providing patient drug information and consumer and patient advocacy groups. In January 1997, HHS Secretary Donna Shalala accepted the action plan, which outlined the consensus on the components of useful information.

Karen Oster of the National Association of Boards of Pharmacy described her organization's role in contracting for the FDA-funded study and obtaining cooperation from state boards of pharmacy. The boards helped in the random selection of pharmacies and by providing "patient observers" to present prescriptions and obtain any written patient information.

Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research, discussed the importance of written information in the context of FDA's effort to move the risk management system for drugs forward. She cautioned against underestimating the magnitude of the task. A century or more of a professional model that didn't trust patients with information has created much inertia to be overcome, she said.

Current Study

Last year's study assessed the quality of written information voluntarily handed out with prescriptions at a random sampling of about 300 community pharmacies in eight states in the East, Midwest, South West and North West. Principal investigators were Bonnie L. Svarstad, Ph.D., and Dara C. Bultman, Ph.D., R.Ph., of the University of Wisconsin.

Svarstad noted that "remarkable progress" had been made in the percentage of prescriptions dispensed with written information. "This suggests that the provision of written prescription information is becoming a routine practice in community pharmacies," she said in her report. The 87 percent rate found in the study showed a large increase from the rates found in previous FDA studies using a consumer-recall methodology—16 percent in 1982 and 59 percent in 1994.

The Svarstad study also examined the quality of the information, which hadn't been done in previous studies. A nine-member national expert panel cross-checked the information sheets against a drug-specific evaluation form. The form listed 10 general criteria, based on the action plan's components of useful information, and 28 to 32 sub-criteria tailored to the specific drugs purchased in the study. The drugs, prescription-strength ibuprofen, amoxicillin and

paroxetine, were chosen to keep the study affordable and provide patient observers with a reasonable cover story for buying all three at once.

Svarstad said more than 75 percent of the patient information sheets examined received "high ratings" in such criteria as the drug and its benefits, adverse reactions, an unbiased tone and content, legibility, comprehensibility, scientific accuracy and inclusion of a disclaimer. Improvement was needed in directions, contraindications, precautions, storage, general information, details about the publisher and date of publication. To achieve a high rating, an information sheet needed to meet most of the criteria and sub-criteria.

She noted limitations of the study included granting equal weight to criteria and sub-criteria, self-selection of the states in the study, variability in sampling procedures, limited training of patient-observers and lack of consumers in the evaluation procedures.

Participants held lively discussions in the breakout sessions. Recommendations for consumer input varied from adding consumer representatives to the expert panels to creating separate consumer panels to assess comprehensibility and legibility. Other issues raised were giving some criteria more weight, setting minimum standards or thresholds for usefulness and including mail-order and non-retail pharmacies in the final study.